K093339 p1/2

Mortara

Abbreviated 510(k) Notification

FEB 19 2010

510(k): ELI PC Electrocardiograph Device Summary

Submitter:

Date: October 23, 2009

Charles Morreale, Manager of Regulatory Affairs
Mortara Instrument, Inc.
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Milwaukee, WI 53224
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Contact: Charles Morreale (see above)

Trade Name: ELI PC Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S.E. is claimed:

The Mortara Instruments ELI PC is substantially equivalent to the legally marketed devices presently in distribution:

- Mortara Instrument ELI 350 Electrocardiograph (K082946)
- Midmark Brentwood IQmark-ECG Analysis System (K955023)

Description:

The proposed Mortara Instrument ELI PC utilizes previously approved predicate Mortara legacy technology and design features from the Mortara electrocardiograph device family, together with other current industry technologies, to achieve a highly reliable electrocardiograph. The ELI PC is a standard 12-lead interpretive electrocardiograph system that is indicated for use by qualified medical professionals in a clinical setting. The ELI PC combines proprietary hardware and an off-the-shelf personal computer. The concept behind the ELI PC is to provide the user with an acquisition module that can transfer the acquired ECG record to a PC for the processing, display, printing and storage. The device may be used in medical clinics and offices of any size, to include Clinical Research Organizations.

The system will be based on two major components:

- A wireless acquisition module with memory (WAM PC) and USB-transceiver key (UTK) combination that will allow the acquisition of a 12-lead ECG that will be stored on the module and subsequently wirelessly transmitted to a PC Station. The Wireless Acquisition Module system will operate at 2.4GHz.
- A software Application (MEPA) that will receive the ECG from the WAM PC and will communicate bi-directionally to the Clinical Server (CTS) and gather/transmit information about the patient's demographics, visit information as well as acquired ECG data. The application controls user access and authentication, submits the resulting ECG and demographic and visit information to the Clinical Server and allows the user to select the appropriate visit protocol and enter patient's demographic and visit data.

The wireless acquisition module with memory (WAM PC) and USB-transceiver key (UTK) combination will be able to acquire multi-lead ECG signals, store the record on the module in an internal non-volatile memory and subsequently wirelessly transmit the record to a PC Station. The PC side of the system will receive the record and will process it. The received ECG data will be first analyzed to determined the quality of the ECG, then the

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record will be analyzed using the Mortara Resting Interpretation (adults and pediatric). The proprietary software configuration incorporates Mortara's VERITAS™ interpretive algorithms. The analyzed ECG will be displayed on the PC screen and will include all the measurements performed by the Interpretation algorithm and the text of the automatic analysis. The user will have the possibility to edit the patient demographic data and, in some versions of the product, also the Interpretation text.

The acquisition module (WAM or ELI series) can be offered in various models, with or without internal printer, depending on the market and the customers' requirements. The WAM PC acquisition module requires use of a supplied Mortara proprietary 10-wire ECG patient cable for patient connection. The cable is unique to the WAM PC and is distributed as a device component with the WAM PC.

The UTK will interface to the PC host via a USB 2.0 compliant interface and a USB type-A connector. The USB connection will transfer data from the UTK to the PC host. The user will be able to store the record on the local hard disk or on a networked server. In addition, printouts will be possible as well as file export in several formats (DICOM, UNIPRO32, XML, FDA-XML). The ELI PC is capable of being interfaced with Hospital Information Systems (or similar) in order to receive patient demographics.

Intended Use:

The intended purpose of the ELI PC Electrocardiograph system is to collect and wirelessly transmit in real time or deferred mode 12-lead (typically) resting Electrocardiograms from patients to a host PC system participating. The complete system includes an acquisition Module WAM PC with patient applied part, the USB Transceiver Key for WAM PC which attaches to a host PC, and the PC Application MEPA to connect bi-directionally to the Clinical Server (CTS) and gather/transmit information about the patient's demographics, visit information as well as acquired ECG data. The WAM PC part of the device will be used in a medically equipped room in a patient environment, and will be in direct contact with the patient. The MEPA software and the UTK key may be installed in an office computer in a normal room.

The patient population for which the device will be used may be healthy or diseased of any age. Patients will usually be ambulatory, however the patient will be in a supine position for ECG acquisition.

Operating environments are general hospitals but may also be used in specialized hospitals that participate with research protocols. Operators of the device will be medical doctors or qualified ECG technicians. The device is intended to be used frequently, in normal office hours and in normal lighting conditions.

Indications for Use:

The proposed Mortara ELI PC Electrocardiograph is a non-invasive prescription device

- The ELI-PC device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use for patients of any age, diseased or non-diseased.
- The device is indicated for use to provide interpretation of the data for consideration by a physician. The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements. It is not intended as a sole means of diagnosis.
- The device is not intended to be used as a vital signs physiological monitor.
- It is not designed for out of hospital transport.
- It is not designed for use in highly invasive environments, such as an operating theatre.
- The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 19 2010

Mr. Charles Morreale
Regulatory Affairs Manager
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224 - 3431

Re: K093339
Device Name: ELI PC Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: February 12, 2010
Received: February 16, 2010

Dear Mr. Morreale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093339

Device Name: **Mortara ELI PC Electrocardiograph**

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093339